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WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

On Writ of Certiorari
to the Vermont Supreme Court

BRIEF OF THE TEXAS MEDICAL ASSOCIATION, TEXAS MEDICAL LIABILITY TRUST, AND NORTH CAROLINA MEDICAL SOCIETY AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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Brockert, et al. v. Wyeth Pharmaceuticals, et al.,
Cause No. 2003-49357, In the 151st Judicial
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In re Prempro Prods. Liab. Litig.,
MDL Docket No. 4:03CV1507-WRW
(E.D. Ark. June 15, 2006) 21

In re Vioxx Prods. Liab. Litig.,
501 F. Supp. 2d 776 (E.D. La. July 3, 2007) .. 21

Ledbetter v. Merck & Co., Inc.,
Master Docket No. 2005-59499, 157th Judicial
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McNeil v. Wyeth, 462 F.3d 364 (5th Cir. 2006) .. 20

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IRC section 501c6 1

Tex. Civ. Prac. & Rem. Code § 82.007(a) *et seq.*
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REGULATIONS

71 Fed. Reg. 3992 (Jan. 24, 2006) 22

OTHER AUTHORITIES

American Medical Association, *Principles of Medical Ethics* (2001), *available at* http://www.ama-assn.org/ama/pub/category/2512.html (last visited August 13, 2008) 14

Committee on the Assessment of the US Drug Safety System, Board on Population Health and Public Health Practice, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (Alina Baciu, Kathleen Stratton & Sheila P. Burke eds., National Academies Press 2006). 7

Curfman, Gregory D., Stephen Morrissey & Jeffrey M. Drazen, *A Pivotal Medical-Device Case,* 358 New Eng. J. Med. 76 (2008). 5, 14, 17

Curfman, Gregory D., Stephen Morrissey & Jeffrey M. Drazen, *Why Doctors Should Worry About Preemption,* 359 New. Eng. J. Med. 1 (2008) 18, 19

FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3992 (Jan. 24, 2006) 22, 23

FDA Drug Bulletin, Vol. 12, No. 1 (April 1982) ... 8

Glantz, Leonard H. & George J. Annas, *The FDA, Preemption, and the Supreme Court,* 358 New Eng. J. Med. 1883 (2008). 15, 16

Gostin, Lawrence O., *The Deregulatory Effects of Preempting Tort Litigation: FDA Regulation of Medical Devices*, 299 J. Am. Med. Ass'n 2313 (2008). 7

Hampton, Tracy, *Experts Weigh in on Promotion, Prescription of Off-Label Drugs*, 297 J. Am. Med. Ass'n 683 (2007). 8, 11

Harris County Medical Society of Ethics, *Principles of Medical Ethics* (2001), *available at* http://hcms.org/Template.aspx?id=247 (last visited August 13, 2008). 14

Higashi, Takahiro, et al., *The Quality of Pharmacologic Care for Vulnerable Older Patients*, 140 Ann. Intern. Med. 714, 714-720 (2004) 25

Kesselheim, Aaron S. & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. Am. Med. Ass'n 308 (2007). 7, 15

Kessler, David A. & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims*, 96 Geo. L.J. 461 (2008) 15

Korobkin, Russell, *Who Should Protect the Public? The Supreme Court and Medical Device Regulation*, 357 New Eng. J. Med. 1650 (2007) 5, 7

McGlynn, Elizabeth, et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 N. Eng. J. Med. 2635 (2003). 25

Mitka, Mike, *Critics Say FDA's Off-Label Guidance Allows Marketing Disguised as Science*, 299 J. Am. Med. Ass'n 1759 (2008). 11

Patsner, Bruce, *Promotion of Off-Label Uses of Prescription Medical Products: FDA's Proposed New Guidance*, Health Law Perspectives (June 2008), *available at* http://www.law.uh.edu/healthlaw/perspectives/homepage.asp (last visited August 13, 2008). 13

Psaty, Bruce M. & Wayne Ray, *FDA Guidance on Off-Label Promotion and the State of the Literature From Sponsors*, 299 J. Am. Med. Ass'n 1949 (2008), *available at* http://jama.ama-assn.org/cgi/content/full/299/16/1949 (last visited August 13, 2008). 9, 10

Riegel v. Medtronics, Amicus Br., *available at* http://www.wlf.org/ upload/RIEGEL-%20WLF%20Amicus%20Brief.pdf (last visited August 13, 2008). 19

Shrank, William H., et al., *The Quality of Pharmacologic Care for Adults in the United States*, 44(10) Medical Care 936 (2006). 24

Stafford, Randall S., *Regulating Off-Label Drug Use – Rethinking the Role of the FDA*, 358 New Eng. J. Med. 1427 (2008) 8, 9, 10

Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (2007), *available at* http://www.bespacific.com/mt/archives/016720.html (last visited August 13, 2008). 5

Troy, Daniel E., *The Patient's Interest in FDA Preemption*, Ave Maria L. (forthcoming), *available at* http://www.federalismproject.org/preemption/papers/Troy_Patients_Interest_in_FDA_Preemption.pdf (last visited August 13, 2008). 23

U.S. Food & Drug Administration, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (2008), *available at* http://www.fda.gov/oc/op/goodreprint.html (last visited August 13, 2008) . . . 9

U.S. Food & Drug Administration, Subcommittee on Science & Technology, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology* (2007), *available at* http://www.bespacific.com/mt.archives/016720.html (last visited August 13, 2008) . . . 7

U.S. Government Accountability Office, GAO-06-402, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* (2006), *available at* http://www.goa.gov/new.items/d06402.pdf (last visited August 13, 2008). 6

U.S. Government Accountability Office, GAO-08-835, *Prescription Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses* (2008), *available at* http://www.goa.gov/new.items/d08835.pdf (last visited August 13, 2008). . . . 12

INTEREST OF *AMICI CURIAE*[1]

The Texas Medical Association ("TMA") is a medical professional membership association (an IRC section 501c6 Texas non-profit corporation) of over 43,000 physicians licensed by the State of Texas, medical residents and medical students. The interests that the Texas Medical Association seeks to protect through this lawsuit are germane to its organizational purpose. One mission of TMA—in fact, its primary mission—is to improve the health of all Texans by being an advocate for patients and the profession of medicine. By filing this brief, TMA is seeking to limit the adverse consequences for patients and physician defendants in medical professional liability litigation when the primary defendant is in fact the drug manufacturer.

The Texas Medical Liability Trust ("TMLT") is a not-for-profit health care liability claim trust owned by its physician policyholders. TMLT was created in 1979, as a result of a legislatively-recognized health care and medical malpractice crisis, to provide an affordable and stable source of professional liability insurance to Texas physicians. TMLT is an independent insurer writing professional liability policies for more than 14,000 Texas physicians and

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[1] Pursuant to Rule 37.6, *Amici Curiae* state that no counsel for a party authored this brief in whole or in part, and that no party or counsel for a party made a monetary contribution intended to fund this brief's preparation or submission. Each party has consented to the filing of this brief. The parties' letters of consent are filed with the Court.

health care providers. TMLT is extensively involved in underwriting and risk management matters for the health care industry, and this requires TMLT to maintain knowledge and expertise of insurance industry standards as well as jurisprudential standards that affect liability insurance procurement and costs in Texas. TMLT is vitally interested in the consistency and predictability of Texas state and federal courts' decision making in cases involving professional liability of physicians and health care providers.

The North Carolina Medical Society (the "Medical Society") is the largest physician organization in North Carolina. Originally founded in 1849, more than 150 years later, the Medical Society has approximately 11,000 members. The Medical Society unifies doctors across North Carolina in all specialties and work settings on issues related to, *inter alia*: the physician-patient relationship, health regulation, and patient safety. As the largest physician organization in North Carolina, the Medical Society devotes significant resources to advocating physician viewpoints in the public policy arena. Specifically, the Medical Society and its member physicians take an active role in issues addressed by private companies, institutions, and the state government and work to ensure that the views of the medical community are presented in an organized and effective fashion.

SUMMARY OF THE ARGUMENT

Federal preemption of liability of pharmaceutical manufacturers for labeling and warning issues would represent an unwarranted expansion of federal

regulatory authority into the healthcare system. Physicians have a vital interest in the delivery of quality patient care, and prescription medications are an important tool in the physician's arsenal of healthcare weapons. However, the medical and pharmaceutical communities operate in an environment in which critical checks and balances, developed over decades, maximize the quality of patient care and minimize untoward events. A policy that extends protection from legal oversight to a single member of the healthcare community would disrupt this fragile system.

First, the notion that the FDA alone can effectively monitor all pharmaceutical industry members and their products is unrealistic. Analyses by medical scientists and government reviewers corroborate that the FDA is lacking in more than one respect in its ability to police such a large and diverse industry. Post-marketing monitoring of drug safety is a well-documented weakness in an already overburdened regulatory scheme. The policy of the medical community should be to enhance every reasonable mechanism that results in a better informed patient and physician population and, thereby, greater patient safety.

Second, if manufacturers are insulated from liability, physicians may find themselves as the scapegoat for adverse drug events. Physicians who practice responsible medicine should not be faced with the potential imposition of liability merely for having prescribed an FDA-approved drug. This is particularly true in the instance of "unlabeled" uses of medications, which are tacitly supported by the pharmaceutical

industry and which often account for a large percentage of medication use and sales. It is unlikely that judicial adoption of preemption in favor of pharmaceutical manufacturers will result in the wholesale discontinuation of all lawsuits arising from the use of FDA-approved prescription medications. Rather, a likely consequence of preemption will be that patients are left with no option but to prosecute claims against their physicians.

Finally, the argument that overwarning would lead to underuse of medications has no support in the peer-reviewed medical journals or in actual practice. It is lack of knowledge and public misperception that most studies have indicated are responsible for underuse of appropriate drugs.

Shielding only one member of the healthcare industry from liability—the pharmaceutical manufacturer—is not equitable, just, or right. The welfare of the patients and equitable healthcare reform should be the primary goal of physicians, the pharmaceutical industry, and the FDA.

ARGUMENT

I. PLACING SOLE AUTHORITY FOR DRUG SAFETY IN THE FDA IS NOT IN THE BEST INTERESTS OF PATIENTS OR THE HEALTHCARE SYSTEM IN GENERAL

The FDA is comprised of intelligent, well-meaning scientists and other professionals who face an almost insurmountable task. However, the FDA arguably does not have the manpower, financial resources, or

statutory authority to adequately police the drug and device industry.[2] Further, FDA approval does not and cannot guarantee long-term drug or device safety, thus post-approval surveillance is important.[3] It is in the context of post-marketing safety surveillance that the FDA's regulatory competence has most frequently been challenged.

While some observers view initial FDA approval of a drug as setting minimum rather than absolute standards for safety and disclosure,[4] the more critical point of contention is the ability of the agency to vigilantly oversee the post-approval safety of drugs it regulates. An analysis of the FDA's ability to conduct post-marketing safety surveillance found serious flaws in the regulatory framework as well as practical limitations. This report, prepared by the General Accounting Office, states:

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[2] David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims*, 96 Geo. L.J. 461, 465 n.12 (2008); Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (2007), *available at* http://www.bespacific.com/mt/archives/016720.html (last visited August 13, 2008).

[3] Gregory D. Curfman, Stephen Morrissey & Jeffrey M. Drazen, *A Pivotal Medical-Device Case*, 358 New Eng. J. Med. 76, 77 (2008).

[4] Russell Korobkin, *Who Should Protect the Public? The Supreme Court and Medical Device Regulation*, 357 New Eng. J. Med. 1650, 1680 (2007).

> FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket drug safety issues. The process has been limited by a lack of clarity about how decisions are made and about organizational roles, insufficient oversight by management, and data constraints. We observed that there is a lack of criteria for determining what safety actions to take and when to take them. FDA faces data constraints that contribute to the difficulty in making postmarket safety decisions. For example, FDA relies on clinical trials, reports of adverse drug reactions, and studies following the use of drugs in ongoing medical care in order to evaluate safety concerns and support its decisions, but each type of data has weaknesses. FDA also lacks authority to require certain studies and has resource limitations for obtaining data.[5]

This analysis, rendered by an agency of the government empowered to make an objective assessment of agency capabilities, should give pause to persons whose true goal is the protection of the public welfare.

Medical commentators echo the sentiment that FDA approval does not and cannot provide an assurance of drug safety in the long term. One writer

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[5] U.S. Government Accountability Office, GAO-06-402, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* (2006), *available at* http://www.goa.gov/new.items/d06402.pdf (last visited August 13, 2008).

has opined that "the premarket approval process can offer, at best, only a modest assurance of long-term safety."[6] Another article in the Journal of the American Medical Association ("JAMA") concluded that "clinical trials and routine regulatory oversight as currently practiced often fail to uncover important adverse effects for widely marketed products."[7] Yet a third observer remarked that "[r]ecent history casts some doubt on the ability of the FDA alone to protect the public and, thus, on the wisdom of dispensing with tort law."[8] These scholars underscore a deficiency in

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[6] Lawrence O. Gostin, *The Deregulatory Effects of Preempting Tort Litigation: FDA Regulation of Medical Devices*, 299 J. Am. Med. Ass'n 2313, 2314 (2008). Gostin also cites to findings of the FDA Science Board ("the scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the ...regulatory system, and hence the safety of the public."); U.S. Food & Drug Administration, Subcommittee on Science & Technology, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology* (2007), available ~~at~~ http://www.bespacific.com/mt.archives/016720.html (last visited August 13, 2008). The commentary quotes from the report of the Institute of Medicine (FDA "lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future."); Committee on the Assessment of the US Drug Safety System, Board on Population Health and Public Health Practice, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (Alina Baciu, Kathleen Stratton & Sheila P. Burke eds., National Academies Press 2006).

[7] Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. Am. Med. Ass'n 308, 311 (2007).

[8] Korobkin, *supra*, note 4, at 1680.

the FDA's ability to conduct critical post-marketing safety surveillance.

Another scenario in which FDA's regulatory capabilities have been challenged is the area of monitoring off-label promotion of pharmaceuticals. It has long been accepted that physicians "may prescribe [drugs] for uses or in treatment regimens or patient populations that are not in approved labeling."[9] The result is that a significant percentage of prescriptions are prescribed for "unlabeled" uses.[10] A concern for patient health arises when physicians are encouraged to prescribe drugs for unlabeled uses through the scientific and medical literature, the integrity of which is subject to question. The conundrum has been described by one commentator:

> The published literature in medicine—a highly formalized scientific discourse among professionals largely free of major financial conflicts of interest—is based fundamentally on trust. While peer review provides some

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[9] FDA Drug Bulletin, Vol. 12, No. 1 (April 1982) ("Such 'unapproved' or, more precisely, 'unlabeled' uses may be appropriate and rational in certain circumstances and may, in fact, reflect approaches to drug therapy that have been extensively reported in the medical literature.") (Attached as Appendix A).

[10] Randall S. Stafford, *Regulating Off-Label Drug Use – Rethinking the Role of the FDA*, 358 New Eng. J. Med. 1427, 1427 (2008); Tracy Hampton, *Experts Weigh in on Promotion, Prescription of Off-Label Drugs*, 297 J. Am. Med. Ass'n 683, 683 (2007).

> important safeguards, the system was not designed to manage major financial conflicts or to withstand the relentless promotion of commercial interests.[11]

FDA regulations concerning distribution of journal articles by pharmaceutical manufacturers traditionally have included two important quality control mechanisms: (1) advanced FDA review of the articles to be distributed and (2) promotion limited to uses for which the manufacturer was working toward FDA evaluation.[12]

The FDA recently announced new rules governing what the agency refers to as "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices."[13] These guidelines are intended to provide rules that govern

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[11] Bruce M. Psaty & Wayne Ray, *FDA Guidance on Off-Label Promotion and the State of the Literature From Sponsors*, 299 J. Am. Med. Ass'n 1949, 1950 (2008), available at http://jama.ama-assn.org/cgi/content/full/299/16/1949 (last visited August 13, 2008).

[12] Stafford, *supra*, note 10, at 1428.

[13] U.S. Food & Drug Administration, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (2008), available at http://www.fda.gov/oc/op/goodreprint.html (last visited August 13, 2008).

the manner in which the pharmaceutical industry may disseminate medical literature the subject of which is "off label" uses of drugs.

Medical commentators who have addressed the subject of so-called "off-label" promotion appear to agree that the new FDA guidelines heighten the potential for mischief in the distribution of information on "off-label" uses of drugs. One author, evaluating the new regulations in JAMA, noted that "there are major limitations in relying on sponsor-distributed literature to regulate off-label use, including the selective publication of studies, the systematic manipulation of the literature, the absence from the literature of critical data necessary for evaluating off-label use, and the potential for undermining the NDA review process."[14]

Another writer remarked that the new rules amount to a "backward shift" in FDA policy that "seems oddly incongruous with current pressures aimed at improving postmarketing drug evaluation."[15] Additionally, the author postulated that "[t]he FDA may be conceding to drug manufacturers the responsibility for regulating their own off-label marketing practices."[16] This possibility provides little comfort to physicians, who rely on information provided by industry to deliver high quality healthcare to their patients. Yet another observer concluded:

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[14] Psaty & Ray, *supra,* note 11, at 1949-51.

[15] Stafford, *supra,* note 10, at 1429.

[16] *Id.*

"The fundamental issue is that people are viewing reprints as science and they believe that science is objective, but industry uses research to advance marketing goals."[17] While the vast majority of information provided by the pharmaceutical industry is of excellent quality, there are notable examples in which unscrupulous behavior has overcome intellectual honesty.[18] Thus, physicians are often left on the horns of a dilemma: disregard information provided by industry that may be scientifically reliable, or rely upon such information at their peril. Neither alternative serves the best interests of the public, the medical profession, or the pharmaceutical industry.

Reasonable oversight of information disseminated by industry to the medical profession seems necessary, but this task may be beyond the capability of an agency whose resources are limited. A report was issued by the General Accounting Office in July 2008, which found serious deficiencies in the FDA's oversight of the promotion of drugs for off-label uses. The report concluded:

> FDA oversees drug promotion for off-label uses by reviewing promotional materials that drug companies submit to the agency. However, because FDA does not have separate oversight

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[17] Mike Mitka, *Critics Say FDA's Off-Label Guidance Allows Marketing Disguised as Science*, 299 J. Am. Med. Ass'n 1759, 1759 (2008).

[18] Tracy Hampton, *Experts Weigh in on Promotion, Prescription of Off-Label Drugs*, 297 J. Am. Med. Ass'n 683, 684 (2007).

activities to specifically capture off-label promotion, its oversight occurs within a broader process that targets a variety of promotional violations. Furthermore, FDA reports it is unable to review all submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health. However, FDA does not prioritize its reviews in a systematic manner but rather relies on its staff to sort through large volumes of material and select submissions for review. FDA is also hampered by the lack of a system that consistently tracks the receipt and review of submitted materials. To address these shortcomings, GAO recommended in 2006 that FDA track which materials it has reviewed. FDA has not acted on this recommendation and still lacks a standardized tracking system to monitor its review efforts. GAO believes that this recommendation remains valid. In addition to its reviews, FDA conducts monitoring and surveillance to identify violations that would not be identified through its review of submitted material—for instance, discussions between doctors and sales representatives. These efforts are also limited because FDA cannot observe all off-label promotion activities as they can take many forms and occur in a myriad of places.[19]

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[19] U.S. Government Accountability Office, GAO-08-835, *Prescription Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses* (2008), *available at* http://www.goa.gov/new.items/d08835.pdf (last visited August 13, 2008).

It is apparent that "[t]he concern about how to view scientific literature disseminated by manufacturers with a marketing agenda is a legitimate one and will likely not go away" in the foreseeable future.[20] Physicians and, by extension, their patients, are vulnerable to being misinformed when the agency responsible for policing communications by and from pharmaceutical companies is understaffed and therefore unable to perform this critical task.

Thus, in both post-marketing safety surveillance and pharmaceutical company promotion of its products, the FDA arguably is incapable of effectively fulfilling its regulatory obligations. This observation is not a criticism of the individuals who work at the FDA or the fine work this agency is capable of doing, but rather, recognition that the pharmaceutical industry presents oversight challenges that would tax even the most well-equipped agency.

II. PHYSICIANS MUST CONSIDER THE IMPACT OF PREEMPTION ON THEIR PATIENT POPULATION AND THE MEDICAL COMMUNITY IN GENERAL

The physician-patient "relationship is based on trust and gives rise to a physician's ethical obligation to place patient's welfare above their own self-interest

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[20] Bruce Patsner, *Promotion of Off-Label Uses of Prescription Medical Products: FDA's Proposed New Guidance*, Health Law Perspectives (June 2008), available at: http://www.law.uh.edu/healthlaw/perspectives/homepage.asp (last visited August 13, 2008).

and above obligations to other groups and to advocate for their patients' welfare. A physician has a duty to use sound medical judgment, and to keep the best interests of the patient paramount."[21] As a member of the medical profession, a physician must recognize "responsibility to patients first and foremost, as well as to society, to other health professionals, and to self."[22]

Physicians must first consider the consequences to their patients of momentous public policy issues such as preemption. Articles in the leading journals in America have addressed the potential consequences of preemption on society. These authorities oppose any policy that would provide a blanket protection exclusively to drug and device companies without a corresponding right to seek legal redress.[23] A recent editorial in the Journal of the American Medical

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[21] Harris County Medical Society of Ethics, *Principles of Medical Ethics* (2001), *available at* http://hcms.org/Template.aspx?id=247 (last visited August 13, 2008).

[22] American Medical Association, *Principles of Medical Ethics* (2001), *available at* http://www.ama-assn.org/ama/pub/category/2512.html (last visited August 13, 2008), states:

> III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
>
> * * *
>
> VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

[23] Curfman, *supra* note 3.

Association provided one view of the problem, focusing on the need to curb frivolous lawsuits, but recognizing the negative impact of preemption on the nation's problem of poorly defined or inadequately presented drug risk information.[24] This commentary recognizes that there are competing interests at work in the preemption debate.

A 2007 study examined the historical impact of the justice system on drug safety.[25] The article noted that this process serves a productive role in a complex intersection of the justice system, the regulatory apparatus, and science. Physicians do not condone unfounded legal claims or necessarily believe the tort system is the most efficient tool by which drug safety may be enhanced. Nonetheless, Amici disfavor a social policy in which patients injured by poorly designed—but FDA-approved—medical devices have no recourse.[26] Each of these problems deserves attention from the healthcare community, including the pharmaceutical community.

History shows that incidents do occur in which physicians prescribe and their patients are exposed to drugs and devices that result in avoidable harms. When untoward events occur and responsibility must be assessed, the interests of all participants in the

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[24] Kesselheim, *supra*, note 7.

[25] *Id.* at 309.

[26] *See* Leonard H. Glantz & George J. Annas, *The FDA, Preemption, and the Supreme Court*, 358 New Eng. J. Med. 1883, 1885 (2008).

healthcare community should be considered. Under the present scenario, however, the federal preemption doctrine focuses solely on protecting the interests of drug and device manufacturers. "The preemption doctrine plays a constructive role in the allocation of regulatory authority over national industries. But its purpose has never been to grant broad legal immunity to private industry."[27] It would be a disservice indeed if the party most responsible for the safety of drugs and devices were cloaked in a protective shield of preemption while healthcare providers and patients were left to fend for themselves.

The February 2, 2008 New England Journal of Medicine included an important editorial on this subject.[28] Although addressing the topic of preemption in the device setting, the policy issue reached is the same and the conclusion of the authors consistent:

> Ultimately, we believe that the pivotal question for the justices in *Riegel v. Medtronic* resides in what is in the best interest of American society. Is it in the people's interest to shield medical device companies from product-liability claims? Would such a decision benefit patients by making more lifesaving medical devices available, or would there be adverse effects on the overall safety of devices? Is the FDA premarketing approval process sufficiently rigorous and comprehensive to justify

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[27] *Id.*

[28] *Id.*

> immunization of the industry against tort claims? And if medical-device manufacturers are shielded from liability, what about drug manufacturers? Or would society be better served if patients retained their right to seek legal redress when they believed they had been damaged by a faulty medical device? In the long run, would this result in safer medical devices for patients?
>
> If Congress later concludes that the Supreme Court has come to the wrong conclusion — that is, a conclusion that is too restrictive of patients' legal prerogatives and does not serve the public interest — Congress can then act to clarify the law and leave open the possibility that patients injured by devices or drugs can seek legal redress.
>
> But by rejecting Medtronic's plea for immunity, the Supreme Court can act now to protect patients. From time to time, the Court agrees to hear a case that may have major, even momentous, implications for health care. *Riegel v. Medtronic* is such a case.[29]

These venerable authorities observe that the benefits of providing absolute immunity to drug and device manufacturers is outweighed by the harm to patients and the negative ramifications for physicians. More importantly the ethical creed by which physicians serve would be disrupted by a policy that placed the

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[29] Curfman, *supra*, note 3, at 77.

burden of regulatory, scientific, or corporate failures on the backs of individuals.

Most recently, the New England Journal of Medicine published a Perspective in its July 3, 2008 edition. The editorial unabashedly challenges the rationale for preemption and remarks that "Congress, not unelected appointees of a federal agency, has the power to decide whether preemption should apply."[30] Further, while "frivolous lawsuits should not be condoned," physicians must speak up against any policy decision that will "result in drugs and devices that are less safe and will thereby undermine a national effort to improve patient safety."[31] Finally, "[i]n stripping patients of their right to seek redress through due process of law, preemption of common-law tort actions is not only unjust, but will also result in the reduced safety of drugs and medical devices for the American people."[32]

There is a strong consensus in the medical community that the interests of patients demand respect and deserve protection. Physicians play a critical role in these tasks. Hence, there is a responsibility for ethical physicians to speak up when action is contemplated that disserves the interests of patients and the medical community at large.

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[30] Gregory D. Curfman, Stephen Morrissey & Jeffrey M. Drazen, *Why Doctors Should Worry About Preemption*, 359 New. Eng. J. Med. 1, 1 (2008).

[31] *Id.* at 2.

[32] *Id.* at 3.

III. PHYSICIANS SUPPORT HEALTHCARE REFORM MEASURES, BUT PIECEMEAL ADOPTION OF PREEMPTION IS NOT EQUITABLE

Physicians eschew any process that detracts from their goal of delivering high quality, economical healthcare to their patients. Tort litigation is an undesirable, but historical, component of the medical and justice systems in America. Physician organizations across the country lobby for tort reform that recognizes the interests of both physicians and patients. Physicians realize that unfortunate outcomes do occur, and the legal system plays an essential role in resolving disputes when they do arise. Nonetheless, the medical community does not favor, and in fact discourages, irresponsible lawsuits.

It is unlikely that the judicial adoption of preemption in favor of pharmaceutical manufacturers will end lawsuits arising from the use of FDA-approved drugs. One potential consequence of preemption would be that patients would be left with no option but to prosecute claims against their physicians.[33] This possible outcome would be unjust indeed.

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[33] *Id.* at 3; *see also* the Amicus Brief filed in *Riegel v. Medtronics* in which it is suggested that physicians may be vulnerable. *Riegel v. Medtronics* Amicus Br. 14, *available at* http://www.wlf.org/upload/RIEGEL-%20WLF%20Amicus%20Brief.pdf (last visited August 13, 2008).

A cogent example of the potential negative consequences of preemption for healthcare providers is found in the case at bar. Petitioner's brief contains a recitation of facts emphasizing that the healthcare provider committed two departures from the strict terms of the product labeling. Petitioner remarks that Ms. Levine's healthcare provider administered "double the labeled amount" of drug and thereafter took action "even though the labeling" instructed a different course of care. It is unfortunate that, in the pharmaceutical litigation setting, industry is often overcome with the temptation to attempt to shift responsibility to the healthcare provider for untoward results that inevitably occur. Left unanswered is the question of whether the healthcare provider was acting as a reasonable and prudent provider under the facts of the case. Further, it is critical to investigate whether the actions of the healthcare provider were known to industry to be the usual and customary procedures involving the subject drug.[34] In the context of preemption, these issues unfortunately would never merit attention.

Two recent mass tort litigations also provide evidence of the uncertainty that is fostered by the judicial adoption *vel non* of preemption. In the Vioxx

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[34] *See McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006)) ("In sum, because the widespread long-term use of Reglan suggests that Wyeth's indication for use for not more than twelve weeks was widely disregarded, a jury could infer that the warning was ineffective and therefore inadequate. It follows that Wyeth had a duty, under Texas law, adequately to warn the learned intermediary of known risks with long term use and not to be misleading as to that risk.").

litigation, the presiding federal judge, the Honorable Eldon Fallon, not only ruled against the defendant drug company on the issue of preemption, he chastised the FDA for the manner in which it implemented its preemption policy.[35] Conversely, a Texas state court judge granted a drug company motion based on a confusing, multi-faceted argument that mixed state and federal preemption allegations.[36] In the hormone replacement therapy litigation, presiding Federal District Judge William Wilson denied a motion for relief based on preemption.[37] A Texas state court judge granted a motion in a hormone replacement case based on similar grounds, though no written opinion was issued.[38] These cases exemplify the difficulty and unpredictability in judicially adopting a controversial and potentially unwise policy such as preemption.

Another question that remains is whether physicians are entitled to the same shield of preemption as industry. By any application of principles of fairness and justice, healthcare providers

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[35] *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 788 (E.D. La. July 3, 2007).

[36] *Ledbetter v. Merck & Co., Inc.*, Master Docket No. 2005-59499, 157th Judicial District Court of Harris County, Texas (no publication) (attached at Appendix B).

[37] *In re Prempro Prods. Liab. Litig.*, MDL Docket No. 4:03CV1507-WRW (E.D. Ark. June 15, 2006).

[38] *Susan Brockert, et al. v. Wyeth Pharmaceuticals, et al.*, Cause No. 2003-49357, In the 151st Judicial District Court of Harris County, Texas.

should receive the same measure of protection as drug companies if the physicians utilize or prescribe FDA-approved drugs in a reasonable and prudent manner.[39] Unfortunately, in the evolving common law environment, this issue is not presented to the court for decision.

The FDA and industry have also addressed this issue only minimally. The FDA preamble[40] is not explicit in the effect of preemption on doctors; the preamble includes this comment: "Preemption would include not only claims against manufacturers as described above, but also against health care practitioners for claims related to dissemination of risk information to patients beyond what is included in the

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[39] A Texas statute provides a rebuttable presumption that the defendants in a product liability action, including the health care provider, "are not liable with respect to the allegations involving failure to provide adequate warnings or information" if the warnings that accompanied the product "were those approved" by the FDA, but this presumption may be rebutted if the claimant establishes that the defendant "withheld from or misrepresented" to the FDA "required information" that was "causally related" to the claimant's injury. TEX. CIV. PRAC. & REM. CODE § 82.007(a) *et seq.* (Vernon 2003). Ironically, state statutes such as this may no longer have application if preemption forbids any type of state "requirements" concerning drug regulation or labeling.

[40] FDA, Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3992 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

labeling. (*See, e.g., Bowman v. Songer*, 820 P.2d 1110 (Col. 1991).)"[41]

One industry commentator has opined: "Notably, although FDA disclaims authority to regulate medical practice, consistent with its well-established policy of noninterference in the practice of medicine, the preamble twice makes clear that the FDA intends for its regulation of risk information for prescription drugs to shield health care practitioners from state-law claims."[42]

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[41] *Id.* at 3936. It is not clear why the FDA cites to *Bowman*. This lawsuit involved an allegation by the defendant physician that he was unfairly held to the standard of care of a drug manufacturer by introduction into evidence of the Physicians' Desk Reference. The court held:

> "In *Hamilton v. Hardy*, 37 Colo. App. 375, 380, 549 P.2d 1099, 1104 (1976), our court of appeals cited *Crouch v. Most*, 78 N. Mex. 406, 432 P.2d 250 (1967), in stating that 'a manufacturer's warnings do not set an absolute standard of care. . . . The standard by which a physician's conduct is judged is an objective community standard. Reliance solely on the manufacturer's warnings may or may not have been within the standard of medical practice in Denver at that time.' Thus, admission of the excerpt from the Physicians' Desk Reference was proper to aid the jury in determining whether Bowman's actions were consistent with the standard of care, and did not place upon him the product manufacturer's liability."

An adverse judgment against the physician was affirmed.

[42] Daniel E. Troy, *The Patient's Interest in FDA Preemption*, Ave Maria L. (forthcoming), *available at* http://www.federalismproject.org/preemption/papers/Troy_Patients_Interest_in_FDA_Preemption.pdf (last visited August 13, 2008).

Unfortunately, there is little certainty what the eventual impact of preemption may be on physicians in the tort litigation setting. The issue in the case at bar is clear however. Extending a shield of implied preemption to one member of the healthcare industry is not the solution. Physicians advocate the adoption of litigation reform measures that would serve the interests of all members of the healthcare community, not just the pharmaceutical industry.

IV. ONE KEY PREMISE UPON WHICH PREEMPTION IS BASED – CONCERNS ABOUT OVERWARNING – IS UNFOUNDED

One of the arguments presented in support of the adoption of preemption is that the current system fosters overwarning of drug risks. The available evidence does not support the conclusion that overwarning is precipitated by the legal system, but rather that inadequate use of drugs is more likely due to patient misperceptions and physicians' lack of knowledge about available drug treatments.

There is evidence that improvements can be made in various facets of medical care in the United States.[43] Preempting tort claims against drug manufacturers is not the panacea for the nation's ills. Rather, the medical community advocates broadscale and continuing improvement in areas in which it has been

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[43] *See, e.g.*, William H. Shrank, et al., *The Quality of Pharmacologic Care for Adults in the United States*, 44(10) Medical Care 936, 940 (2006).

proven to be justified: prescribing indicated medications, monitoring, education, and continuity of care.[44]

In conclusion, while all participants in the healthcare community should advocate the efficient and timely use of appropriate medical therapy, "overwarning" precipitated by tort litigation is not documented to be the primary cause of underuse of medications. The empirical data tends to show that increasing the knowledge of physicians and patients will result in improvement in prescribing habits and overall patient care. Hence, a concern of "overwarning" should not be relied upon as a basis for adopting preemption.

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[44] Takahiro Higashi, et al., *The Quality of Pharmacologic Care for Vulnerable Older Patients*, 140 Ann. Intern. Med. 714, 714-720 (2004). The article also cites to "possible reasons" for "the underuse of potentially beneficial medications," but fails to mention civil lawsuits as a reason for this deficiency. *See also* Elizabeth McGlynn, et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 N. Eng. J. Med. 2635, 2635-45 (2003).

CONCLUSION

For these reasons, and those stated in Respondent's brief, the judgment of the Vermont Supreme Court should be affirmed.

Respectfully submitted,

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APPENDIX

APPENDIX A

FDA Drug Bulletin
April 1982
Volume 12 Number 1
Pages 4-5

Use of Approved Drugs for Unlabeled Indications

The appropriateness or the legality of prescribing approved drugs for uses not included in their official labeling is sometimes a cause of concern and confusion among practitioners.

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer only for those uses for which the drug's safety and effectiveness have been established and which FDA has approved. These are commonly referred to as "approved uses." This means that adequate and well-controlled clinical trials have documented these uses, and the results of the trials have been reviewed and approved by FDA.

The FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more

precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only. FDA tries to assure that prescription drug information in the package insert accurately and fully reflects the data on safety and effectiveness on which drug approval is based.

APPENDIX B

MASTER DOCKET NO. 2005-59499

**IN THE DISTRICT COURT OF
HARRIS COUNTY, TEXAS
157th JUDICIAL DISTRICT**

**(Trial Court: 151st Dist. Court of
Harris County, Cause No. 2005-58543)**

[Filed April 20, 2007]

Ruby Ledbetter	)
	)
v.	)
	)
Merck & Co., Inc.	)
	)

**Order Granting Defendant's Motion
for Partial Summary Judgment
And Granting Expedited Appeal**

Defendant Merck & Co., Inc. ("Merck") has filed a no evidence motion for partial summary judgment on plaintiff's warning claims. This motion is based on a 2003 Texas statute governing FDA approved warnings. TEX. CIV. PRAC. & REM. CODE ANN. §82.007. Merck argues that §82.007 is preempted by federal law. For reasons stated, the motion is granted.

1. Background

Vioxx (known generically as rofecoxib) is a NSAID (non-steroidal anti-inflammatory drug). This class of drugs includes over the counter medications, such as Advil (ibuprofen) and Aleve (naproxen) and a variety of prescription medicines. NSAIDS work by inhibiting cyclooxygenase (COX), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body that promote certain effects.

In the early 1990s, scientists discovered that the COX enzyme was composed of two forms. COX-1 affects the synthesis or production of prostaglandins responsible for protection of the stomach lining; COX-2 stimulates the prostaglandins that cause pain and inflammation. This belief led to the hypothesis that a selective NSAID, designed to inhibit COX-2, but not COX-1, could offer pain relief without the risk of fatal or debilitating gastrointestinal perforations and ulcers. This led Merck to begin the development of such a drug, which became known as a COX-2 inhibitor. Vioxx is a COX-2 inhibitor.

In December 1994, Merck submitted an Investigational New Drug Application to the FDA seeking approval to conduct studies to test the safety of Vioxx to treat osteoarthritis, rheumatoid arthritis, and pain. In November 1998 Merck submitted a New Drug Application for Vioxx. The FDA reviewed the Merck submission and, as well, convened an Advisory Committee to review the data and make recommendations. On May 20, 1999, the FDA approved Vioxx for sale in the United States.

Vioxx was subjected to a number of studies and trials, including VIGOR, APPROVe, and others. APPROVe was a randomized clinical trial that compared Vioxx to a placebo. The APPROVe study indicated that the use of Vioxx increased the risk of cardiovascular thrombotic events such as myocardial infarctions.

On September 30, 2004, Merck withdrew Vioxx from the market. Thousands of lawsuits ensued across the country. On September 6, 2005, Texas cases were consolidated into this MDL, proceeding. There are currently over 1,000 Vioxx cases in these consolidated Texas proceedings; virtually all of them contain an allegation that Merck failed to provide an adequate warning.

2. Preemption

A. The Texas Act

In 2003, the Texas legislature enacted TEX. CIV. PRAC. & REM. CODE ANN. §82.007, which provides, in part:

> **§ 82.007. Medicines**
>
> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations

involving failure to provide adequate warnings or information if:

> (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended; or

* * * *

(b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:

> (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;

* * * *

TEX. CIV. PRAC. & REM. CODE ANN. §82.007 (hereinafter the "Texas Act"). The Texas Act was one of a number of enactments in 2003 designed to achieve "tort reform" as a result of a perceived lawsuit crisis,

particularly involving the medical arena. This statute has yet to be construed by Texas appellate courts.

There is no question but that the FDA approved the general warnings or information provided by Merck with respect to Vioxx. Plaintiffs rely exclusively upon subsection (b)(1) of the Texas Act in order to rebut the Act's presumption that Merck is not liable for failure to provide an adequate warning.

B. Construction of the Texas Act.

In order to determine whether the Texas Act has been preempted, this Court must first construe the various terms contained in the Act.

1. Burden of Proof.

A threshold question confronting this Court concerns the burden of proof under the Texas Act. Section 82.007 states that a claimant may rebut the presumption in the statute by "establishing" that certain required information was withheld. What does "establish" mean? Merck equates "establish" with "prove" and argues that plaintiffs must prove that such information was withheld or misrepresented by a preponderance of the evidence. Plaintiffs argue that the presumption "bursts" merely upon presenting some evidence that information was withheld. Thus, according to plaintiffs, at the conclusion of plaintiffs' case, the Court would rule as a matter of law whether some evidence of withholding or misrepresentation of evidence was presented, and thereafter, the failure to warn question would be presented to the jury.

Plaintiffs therefore argue that the court, rather than the jury, decides whether information was withheld.

The Court agrees with Merck. Plaintiffs have the burden to "establish" or prove that required information was withheld from or misrepresented to the FDA by a preponderance of the evidence. This is ordinarily a question for the jury.

2. Required Information

To rebut the presumption, plaintiffs must show that "required information" was withheld or misrepresented. "Required information" means that information which is required to be submitted to the FDA pursuant to federal statute and regulations governing pharmaceutical products.

3. Material Information.

The Texas Act next requires that claimants prove that "material and relevant" information was withheld. Not surprisingly, the parties presented two different definitions of materiality.

- Plaintiffs posit that they must merely show "that the allegedly withheld information, if disclosed, would have a natural tendency to influence, or be capable of influencing, a government function."

- Merck, on the other hand, argues that plaintiffs must show "that the allegedly withheld information, if disclosed, in reasonable probability would have led to a different

> regulatory outcome such as refusal to approve Vioxx for marketing or requiring a label change."

Plaintiffs proposed definition is erroneous for several reasons. First, the definition would effectively make any relevant information sufficient to eliminate the presumption. Under the plaintiff's definition, virtually any information would qualify. Since the Texas Act was promulgated in an environment of tort reform, the legislature surely meant that the burden on plaintiffs be more than merely finding "some information" that "might" be capable of influencing the FDA. This Court may consider the circumstances surrounding a statute and the goals sought to be achieved by the legislature in construing a statute. *See Lexington Ins. Co. v. Strayhorn*, 209 S.W.3d 615 (Tex. 2005).

Second, the Texas Act requires that the withheld information be "causally related" to the plaintiff's injury. Unless withheld information would have resulted in some definite change by the FDA, either non-approval of the drug, or a labeling change, such with withheld information could not be causally related to a plaintiff's injury.

Thus, plaintiffs must prove by a preponderance of the evidence that required information was withheld from or misrepresented to the FDA, such that the allegedly withheld or misrepresented information, if disclosed or not misrepresented, would have led to a different regulatory outcome such as refusal to approve Vioxx for marketing or requiring a label change.

4. Relevant Information

The allegedly withheld or misrepresented information must relate to the same injury complained of by plaintiff.

C. Preemption of the Texas Act

The starting point of any preemption analysis concerning the Texas Act is *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001), where the Supreme Court held that state law "fraud on the FDA" claims are preempted by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA"). There, Buckman was a consulting company that assisted a manufacturer to obtain FDA approval for certain medical devices. Plaintiffs were consumers of these devices, who claimed personal injuries; plaintiffs sued Buckman alleging that Buckman made fraudulent representations to the FDA. Plaintiffs claimed that such misrepresentations were a "but for" cause of injuries: had the representations not been made, the FDA would not have approved the device, and plaintiffs would not have been injured. The Supreme Court held that such claims are preempted by the FDCA. The Court reasoned that it is the FDA's exclusive responsibility to "police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. The Court observed that the FDA is empowered to investigate fraud and that citizens may report wrongdoing and petition the agency to take action. *Id.* at 349. Moreover, "fraud-on-the FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient

in state court" resulting in a "deluge" of needless information on the FDA, potentially burdening the agency and delaying release of new products. *Id.* at 351.

Since *Buckman,* several courts have considered statutes similar to the Texas Act. In *Garcia v. Wyeth Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit considered a Michigan law that immunizes a drug manufacturer from products liability suits if the drug was approved by the FDA unless the manufacturer intentionally withheld or misrepresented required information.[1] The court held the Michigan law was preempted to the extent that it permitted a state court to determine whether a drug

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[1] The statute provides, in relevant part: "(5) In a product liability action against a manufacturer or a seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. . . . This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . , and the drug would have not been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

MICH. COMP. LAWS § 600.2946(5).

manufacturer committed fraud on the FDA. *Id.* at 966. However, such "inter-branch-meddling concerns that animated *Buckman*" do not arise when the "FDA *itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Id.* (emphasis in original) Thus, the court held that a plaintiff could only invoke the "fraud on the FDA" exception to the Michigan statute if the FDA itself determines that it was defrauded. Other courts have reached similar conclusions. *See, e.g., Henderson v. Merck & Co.*, 2005 WL 2600220 (E.D. Pa., Oct. 11, 2005); *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1172-74 (D. Ariz. 2005).

Plaintiffs, however, rely on *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), which reached a different conclusion and suggested three reasons why the *Garcia* analysis is flawed. First, plaintiffs correctly note that there is a presumption against preemption. While such a presumption exists, *see Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992), the Supreme Court in *Buckman* expressly held that no such presumption against preemption existed in that case. "The relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." 531 U.S. at 347. Because, in that case, the medical device manufacturer's dealings with the FDA were prompted by federal law, "no presumption against preemption obtains in this case." *Id.* The same analysis must apply with no less force to drug manufacturers. Indeed, the State of Texas, by enacting the Texas Act, has placed the relationship between drug manufacturer and FDA in issue.

Second, plaintiffs argue that *Buckman* is inapplicable since it involved a non-traditional suit based entirely on a fraud on the FDA theory, whereas these suits allege traditional products liability theories. This is a distinction without a difference. Under the Texas Act, in order to pursue a failure to warn case, plaintiffs must prove that required and material information was withheld from the FDA. Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply. The requisite showing under the Texas Act is analogous to and sufficiently equivalent to plaintiffs' asserting a claim of fraud on the FDA that the claim is preempted under *Buckman*.

Finally, plaintiffs argue that the proof required under the Texas Act is different from a "fraud on the FDA" complaint. Plaintiffs argue that mere inadvertent withholding of information is sufficient to puncture the rebuttable presumption of the Texas Act[2], whereas intentional fraud was at issue in *Buckman*, and, indeed, part of the statute in Michigan. This Court is not persuaded by this argument. The logic of *Buckman* was that the FDA promulgates detailed data submission requirements and is fully empowered to investigate wrongful withholding by manufacturers.

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[2] The Court notes that the Texas Act uses the word "misrepresents" which could imply an element of intent, depending on whether the misrepresentation required is intentional or negligent. However, for purposes of this motion, the Court will assume no scienter is required since the statute disjunctively includes "withheld from" as sufficient to eliminate the statutory rebuttable presumption.

531 U.S. at 1017. If anything, the argument that *Buckman* involved a claim with an element of scienter, whereas the Texas Act requires only inadvertent withholding undermines plaintiffs' argument. State courts traditionally adjudicate a party's state of mind, *e.g.*, whether fraud occurs. Indeed, a state court is probably better suited than a federal agency to determine whether an intentional misrepresentation occurred as opposed to an inadvertent omission. The key issue for purpose of presumption analysis is not whether information was intentionally withheld, but whether the federal regulation is so pervasive as to leave no room for state regulation. Given the extent of federal regulation, and the extent to which the FDA is empowered to investigate and regulate drug manufacturers who fail to provide required information, permitting a Texas jury or judge to make the same inquiry would impinge on a uniquely federal issue.

All of the concerns raised by the Supreme Court in *Buckman* would manifest themselves if the motion for summary judgment were denied. *Buckman* noted that manufacturers might "deluge" the FDA with information it neither needed nor wanted in order to defend state tort claims. 531 U.S. at 351. This could potentially impede the regulatory process. The *Buckman* concern of deluging the FDA could well come true if manufacturers were forced to make data submissions defensively in order to ensure that the presumption of the Texas Act remained in place.

There is no question but that the FDA has not made a determination that material and relevant

information was either withheld or misrepresented concerning Vioxx.

C. Severability

Plaintiffs argue that if subsection (b)(1) is preempted, then the entirety of section 82.007 must fall, leaving no presumption that Merck's is not liable with respect to the allegations involving failure to provide adequate warnings. This argument fails. First, plaintiffs can still avail themselves of (b)(1) if the FDA determines that required information was withheld. The issue is who makes the determination—the FDA or a Texas court or jury.

Second, the Texas Act is severable. Texas law currently provides that:

> (c) In a statute that does not contain a provision for severability or nonseverability, if any provision of the statute or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the statute that can be given effect without the invalid provision or application, and to this end the provisions of the statute are severable.

TEX. GOV'T CODE § 311.032(c). Unless the legislature provides for nonseverability, the Government Code provides that the statute is severable. Even if subsection (b)(1) is invalid, the remaining statute can be given effect.

Finally, in passing the Texas Act, the legislature expressly considered the possibility that the law would not survive a *Buckman* analysis.[3] Yet, notwithstanding this forewarning, the legislature did not insert a nonseverability provision into § 82.007.

D. Conclusion on Preemption

For the forgoing reasons, Merck's motion for partial summary judgment is granted and subsection (b)(1) of TEX. CIV. PRAC. & REM. CODE ANN. §82.007 is preempted to the extent that someone other than the FDA is being asked to make the determination. Plaintiffs cannot rely on subsection (b)(1) unless and until the FDA makes the required findings under (b)(1).

3. Merck's Alternative Motion

Merck argued alternatively that even if the Texas Act is not preempted, a no evidence motion for summary judgment should nevertheless be granted. Merck argues that plaintiffs do not have sufficient evidence to rebut the presumption.

In response, plaintiffs submit the affidavits of various experts. However, because of this Court's

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[3] For example, Baylor Law School Dean Bradley Tobin testified in Senate committee hearings that § 82.007 could very well be challenged on *Buckman* grounds. Hearings on Tex. H.B. 4 Before Senate State Affairs Comm., 78th Leg., R.S. at 23-24 (May 5, 2003).

ruling on preemption, it is not necessary to rule on Merck's alternative motion.

Plaintiff's motion to strike Merck's Summary Judgment evidence is Denied.

Plaintiff's claim of failure to warn is hereby severed from this Master Docket and will henceforth be under cause number 2005-59499A and in the original trial court as Cause No. 2005-58543A. The pleadings in this severed cause shall consist of plaintiff's petition(s), defendants' answer(s), Merck's motion for partial summary judgment and all responses, replies, rebuttals and other briefs and memoranda concerning the motion for summary judgment.

This is a final order and is appealable.

It is further ordered that any appeal from this Order be expedited pursuant to Tex. R. Jud. Admin. 13.9(c) as this order is made in MDL pretrial proceedings.

Signed April 19, 2007.

/s/

Hon. Randy Wilson